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Korea determined to make it big in CMO space

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Korea, which is pushing hard to enter the CMO space, is making all efforts. In August 2010, the World Health Organization and the Korea Food & Drug Administration jointly organized the first implementation workshop of WHO guidelines on evaluating similar biotherapeutic products (SBPs) at the global level.

The objective of the workshop was to facilitate implementation of the newly adopted WHO guidelines into the practice of national regulatory authorities. The WHO guidelines were recognized by the workshop participants as a tool for harmonizing regulatory requirements worldwide. By reviewing several case studies, better understanding and consensus on the principles of clinical trial designs emerged.

In the KFDA and WHO workshop, variations in terms of the national requirements for quality, safety and efficacy of these products revealed diversity in the regulatory expectations of different countries and regions. In addition, lack of terminology for the products developed as copy products led to a great diversity in evaluating and naming of these products.

The workshop participants proposed actions such as; NRAs should make efforts to build their capacities for regulation of SBPs and that the WHO should revise WHO guidelines for assuring the quality of products prepared by recombinant DNA technology and continue monitoring progress with the implementation.